Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization

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Summary

Unless Congress acts to reauthorize it, the Food and Drug Administration's (FDA's) authority to collect user fees under the Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250) and, by reference, FDA's obligation to meet related performance goals, will expire on October 1, 2007. According to the President's budget request, in FY2008, funds from a reauthorized MDUFMA would account for an estimated $47.5 million and 200 full-time equivalent employees (FTEs). This would comprise 16.6% of FDA's medical device review budget authority and 13.0% of its medical device review-related FTEs. While these numbers and percentages are not as high as those projected for collection under a similar FDA user fee authority related to prescription drugs (pursuant to the Prescription Drug User Fee Act), they are significant.

For MDUFMA as passed in 2002, the fee amounts and performance goals articulated and incorporated in statute were the result of an agreement between FDA and the medical device industry. In order to facilitate the reauthorization of MDUFMA, in April 2007, the FDA and industry published the results of their negotiations with a notice of an April 30, 2007, public meeting on the topic. According to FDA, during the five years covered by the proposals (through 2012), FDA would receive approximately $287 million from user fees. This represents an increase from the $110 million FDA received during the first four years of the program.

The industry agreement also calls for changes in the fee structure, performance goals, small business relief, and third-party inspection program. In addition, the agreement reflects FDA's initiatives related to the regulation of in vitro diagnostic devices (laboratory tests). (MDUFMA enabled third-party inspections and set standards for the use of reprocessed single-use devices.) The details of the proposed reauthorization of MDUFMA have been incorporated, with a few exceptions, into the Medical Device User Fee Amendments of 2007 (MDUFA 2007). On May 9, 2007, MDUFA 2007 passed the Senate as Title III of the Food and Drug Administration Revitalization Act (S. 1082). On July 11, 2007, the House passed it as Title II of the Food and Drug Administration Amendments Act of 2007 (H.R. 2900). The bills' MDUFA 2007 provisions are similar, but not identical. Differences between them are expected to be addressed in conference. The provisions of MDUFMA and the proposals for MDUFA 2007 are discussed in this report, following an introduction to FDA's medical device review process.

This report will be updated as event warrant.

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Overview: FDA and Medical Device Review

In order to understand the significance of MDUFMA, a basic introduction to FDA and the medical device review process is useful. The United States Food and Drug Administration (FDA) is the agency responsible for ensuring the safety and effectiveness of medical devices in the United States. According to statute, a medical device is

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 §201(h)) (FFDCA).

According to this definition, a medical device can be anything from a tongue depressor to a home pregnancy test to a wheelchair to a pacemaker. Types of medical devices vary widely, as do their respective manufacturing requirements. In part due to the diversity of medical devices, compared to the drug industry, the device industry is more fragmented, smaller (estimated earnings of $80 billion in 2004 compared to the drug industry's estimated $222 billion), and dominated by smaller companies.

FDA is divided into six centers, each charged with regulating a particular type of product. The center within FDA primarily responsible for ensuring the safety and effectiveness of medical devices is the Center for Devices and Radiological Health (CDRH). One other center, the Center for Biologics Evaluation and Research (CBER), regulates some devices—specifically those associated with blood collection and processing procedures, as well as with cellular therapies (e.g., stem cell treatments). Jurisdiction of the centers' medical device review is governed by the FDA Intercenter Agreement between CBER and CDRH (October 31, 1991).[1]

CDRH categorizes medical devices according to their risk into one of three classes: Class I, II, and III. (See **Table 1**.) The risk a device poses, and the regulatory controls required, increase from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification (510(k)) and require only registration with FDA before marketing; most Class II devices require a 510(k) before marketing; and most Class III devices require Premarket Approval (PMA). Most PMAs and some 510(k)s require clinical trials,[2] which are conducted with FDA permission via an investigational device exemption (IDE) that allows a device to be used in a study to gather information on its safety and effectiveness. Devices are reviewed by CBER under a biological license application (BLA).

[1] FDA, "Devices Regulated by CBER," (updated March 15, 2007), at http://www.fda.gov/cber/dap/devlst.htm.

[2] For more information on the regulation and sharing of results from clinical trials, see CRS Report RL32832, *Clinical Trials Reporting and Publication*, by Erin D. Williams, and CRS Report RL32909, *Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule*, by Erin D. Williams.

Table 1. Medical Device Approval Basics

Device Classification	Examples	Safety/Effectiveness Controls	Required Submission
Class I	elastic bandages, examination gloves, and hand-held surgical instruments	General Controls[a]	-*Registration only* unless 510(k) specifically required
Class II	powered wheelchairs, infusion pumps, and surgical drapes	General Controls & Special Controls[b]	-*510(k) clearance* unless exempt -*IDE possible*
Class III	heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators	General Controls & Premarket Approval	-*PMA approval* unless 510(k) specifically permitted -*IDE probable*

a. General controls include five elements: establishment registration (use FDA Form 2891) of companies which are required to register under 21 CFR part 807.20, such as manufacturers, distributors, repackagers and relabelers, and foreign firms; medical device listing (use FDA Form 2892) with FDA of devices to be marketed; manufacturing devices in accordance with the Quality Systems regulation (GMPs) in 21 CFR Part 820; labeling devices in accordance with labeling regulations in 21 CFR Part 801 or 809; and submission of a premarket notification 510(k) before marketing a device. (Most Class I devices are exempt from the premarket notification and/or the Quality System Regulation).

b. Special controls may include special labeling requirements, mandatory and voluntary performance standards and postmarket surveillance.

To supplement a PMA when there are changes in safety and effectiveness data, FDA may require one of four types of submissions: Panel Track Supplements, 180-Day Supplements, Real Time Supplements, and 30-Day Notices. Panel Track Supplements are akin to second entire PMAs. They reflect new indications for use or significant changes in device design or performance, and require substantial clinical data. As artificial heart valve approved for use to replace the aortic valve, and proposed for use in the mitral valve, would require the submission of a Panel Track Supplement. 180-Day Supplements are submitted for significant changes to medical device components, materials, designs, specifications, software, labeling, or color additives. A proposed change in a blood glucose monitoring system from wired to wireless telemetry would require this type of submission. Real Time Supplements are submitted when there are minor changes to the design, software, sterilization or labeling of a device. A change in the storage temperature and expiration dating for an injectable gel would require this type of supplement. 30-Day Notices are submitted for modifications to manufacturing processes or methods, such as a change in the sterilization process.

FDA offers one alternative that can be used in place of a PMA: the Product Development Protocol (PDP). A PDP is based upon early consultation between the sponsor and the FDA, leading to a device development and testing plan acceptable to both parties. It aims to minimize the risk that the sponsor will unknowingly pursue—with the associated waste of capital and other resources—the development of a device that FDA will not approve.

One additional type of submission is a 513(g) request, so named because of the section of the FFDCA that regulates it. 513(g)s enable requesters to obtain information from FDA regarding the regulatory status of their devices or products.

Of all device-related submissions, a PMA (or Panel Track Supplement) is the most rigorous and time consuming application process for manufacturers and review process for the FDA. A 510(k) is significantly less rigorous, and is much more common. The majority of medical devices that come to market do so with 510(k) clearance rather than PMA approval. (See **Table 2**.)

Table 2. Premarket Approvals (PMAs), Panel-Track Supplements, and Premarket Notification (510(k)s), FY2003-FY2006

	PMAs and Panel-Track Supplements	510(k)s[a]
FY2003	50	3,795
FY2004	48	3,383
FY2005	58	3,415
FY2006	51	3,732

Source: MDUFMA quarterly report, at http://www.fda.gov/cdrh/mdufma/reports%5Cquarterlysummary.pdf.

a. The chart excludes 510(k)s that were closed for any reason other than an FDA determination of substantial equivalence (*SE*, which results in FDA *clearance)* or a finding of non-substantial equivalence (*NSE*, which does not result in FDA clearance), for example, when FDA finds that a 510(k) was not required. The number of 510(k)s in the MDUFMA Cohort is subject to change until the cohort is complete.

In the years prior to MDUFMA's enactment, FDA's resources for its device and radiological health programs had increased at a lower rate than its costs.[3] As stated in the House Report to H.R. 3580 (MDUFMA):

> The medical device industry is growing rapidly. The complexity of medical device technology is increasing at an equally rapid pace. Unfortunately, FDA's device review program lacks the resources to keep up with the rapidly growing industry and changing technology. Because prompt approval and clearance of safe and effective medical devices is critical to improving public health, it is the sense of the Committee that adequate funding for the program is essential.[4]

In addition to filing applications for clearance or approval with FDA, device manufacturers must be registered with FDA and file annual reports. In addition, FDA inspects establishments where medical devices that are marketed in the United States are manufactured to assess compliance with FDA's quality system requirements for ensuring good manufacturing practices (GMP) and other applicable requirements. According to the Government Accountability Office (GAO):

> During quality system inspections, FDA investigators examine manufacturing controls, processes, and records. These inspections are FDA's primary means of assuring that the safety and effectiveness of medical devices are not jeopardized by poor manufacturing practices.[5]

In addition to issues raised by medical device review funding and inspection capabilities at FDA, prior to MDUFMA, concerns had also emerged regarding the reprocessing and re-use of medical devices that FDA had cleared or approved as *single use devices* (SUDs). Reprocessing means cleaning and sterilizing a device and verifying that it functions properly. Concerns about SUDs as well as funding and inspections paved the way for Congressional action in 2002 as described in the next section.

[3] FDA, "Medical Device User Fee and Modernization Act; Public Meeting," *Federal Register*, vol. 72, no. 74, p. 19528, (April 18, 2007) at http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=268837241492+0+0+0&WAISaction=retrieve.

[4] U.S. Congress, "House Committee on Energy and Commerce, Medical Device User Fee and Modernization Act of 2002," report to accompany H.R. 3580,107th Cong., 2nd sess., part 1 (Washington: GPO, 2002), pp. 23.)

[5] Government Accountability Office, "Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations," Report to Congress GAO-07-157 (January 2007).

MDUFMA and MDUFA 2007

Prior to the enactment of Medical Device User fee and Modernization Act (P.L. 107-250, hereinafter referred to as MDUFMA), FDA officials met with industry leaders, to agree upon mutually acceptable fee types, amounts, exceptions, and performance goals.[6] The agreement specified that, in return for the additional resources provided by medical device user fees, FDA was expected to meet performance goals defined in a November 14, 2002 letter from the Secretary of the Department of Health and Human Services (HHS) to the Chairman and Ranking Minority Members of the Committee on Health, Education, Labor and Pensions Committee of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representative.[7]

MDUFMA was enacted in order to provide FDA "with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time, and to ensure that reprocessed medical devices are as safe and effective as original devices."[8] MDUFMA amended the FFDCA to enact three significant provisions for medical devices: (1) it established user fees for premarket reviews of devices; (2) it allowed establishment inspections to be conducted by accredited persons (third parties); and (3) it instituted new regulatory requirements for reprocessed single-use devices. FDA's authority for the first of these (the collection of user fees) will expire on October 1, 2007, unless Congress reauthorizes it.

MDUFMA was subsequently amended by two laws: the Medical Device Technical Corrections Act (MDTCA, P.L. 108-214), and the Medical Device User Fee Stabilization Act of 2005 (MDUFSA, P.L. 109-43). Unless otherwise noted, the discussion of MDUFMA that follows incorporates the amendments made by MDTCA and MDUFSA.

In preparation for reauthorization (MDUFA 2007), FDA and industry representatives announced in April 2007 that they had reached a proposed mutual agreement on terms ("FDA Agreement"). Pursuant to MDUFMA (§105), on April 30, 2007, FDA held a public meeting about the FDA Agreement. Attendees expressed general satisfaction with its terms.

The terms of the FDA Agreement were, by and large, incorporated into the Food and Drug Administration Revitalization Act (S. 1082), which the Senate passed on May 9, 2007. They have also been generally incorporated into the Food and Drug Administration Amendments Act of 2007 (H.R. 2900), which the House passed on July 11, 2007. The two bills' MDUFA 2007 provisions are similar, but not identical, as explained below. Differences are expected to be addressed in conference. Like MDUFMA, MDUFA 2007 proposals address both user fee authorities and third-party inspection. The proposed MDUFA 2007 user fee provisions would sunset on October 1, 2012. These as well as other MDUFMA provisions and other related topics, such as the impact that MDUFMA has had on postmarket inspection and enforcement, are discussed in the remainder of this report.

[6] This process was similar to the one used previously during the enactment and reauthorization of the user fee act for prescription drugs, the Prescription Drug User Fee Act (PDUFA). For further information on PDUFA, see CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by Susan Thaul.

[7] This letter is generally referred to as the "FDA Commitment Letter." See 148 Cong. Rec. S11549-01(2002).

[8] Medical Device User Fee and Modernization Act of 2002, H.Rept. 107-728 (October 7, 2002), p. 21.

User Fees

Several important aspects of MDUFMA and MDUFA 2007 are related to user fees, including statutory "triggers" that link FDA's authority to collect and spend user fees to levels of Congressional appropriations, as well as reductions and exemptions to fees, performance goals, and allowable uses of fees.

Triggers

The authority to collect MDUFMA user fees is subject to statutory triggers that prohibit the collection of the fees if direct Congressional appropriations to FDA for salaries and expenses related to devices and radiological health fall below a certain threshold. In 2005, legislation was required to enable the continuation of the MDUFMA user fee program because Congressional appropriations had been lower than required for FY2003 and FY2004. MDUFSA (the 2005 legislation) lowered the MDUFMA triggers retroactively for FY2003 and FY2004 and prospectively for FY2005-FY2007.

According to MDUFSA, FDA's salaries and expense appropriation line for Devices and Radiological Health, exclusive of user fees, must be not more than 1% below $205,720,000, plus statutory adjustments for FY2005-FY2007.[9] For FY2007, this translates into a minimum requirement of $229,334,000. (See **Table 3**.) No statutory trigger has been set for years beyond FY2007. MDUFA 2007 proposes that the MDUFSA trigger language be maintained through FY2012.

Table 3. Statutory Triggers for MDUFMA (FDA's Salaries and Expense Appropriation Line for Devices and Radiological Health, Exclusive of User Fees)

	Appropriated Levels
FY2005 Actual	$214,966,000
FY2006 Minimum Requirement	$222,654,000
FY2007 Minimum Requirement	$229,334,000

Source: FDA Office of Management, "Funding For MDUFMA and ADUFA Triggers," FY2007 Budget Formulation and Presentation, (Feb. 22, 2006), at http://www.fda.gov/oc/oms/ofm/budget/2007/HTML/7UserFeeTriggersBCPPOM.htm.

User Fees, Device Review Budget and FTEs

The amount of FDA's device review budget derived from MDUFMA user fees (private money) has increased almost every year since the act became law. Over the period of FY2003 to FY2008, MDUFMA funding has increased at a much faster rate (220.1%) than direct appropriations from Congress (24.1%).[10] MDUFMA fees comprised less than 7% of FDA's program level device review budget in FY2003, and estimates are that they will comprise over 16% in FY2008. (See **Table 4**.) According to the President's FY2008 budget request, MDUFMA fees would translate into 200 FTEs for that year, or 13% of the FTEs in the device review process (See **Table 5**).

[9] FDA Office of Management, "Funding For MDUFMA and ADUFA Triggers," FY2007 Budget Formulation and Presentation, (February 22, 2006), at http://www.fda.gov/oc/oms/ofm/budget/2007/HTML/7UserFeeTriggersBCPPOM.htm.

[10] Calculation is based upon FY2003 Actuals (MDUFMA: $14,838,000, FDA budget authority: $193,350,000), and the FY2008 President's Budget Request (MDUFMA: $47,500,000, FDA budget authority: $240,122,000).

Table 4. Funding for the Device Review Process Salaries and Expenses, FY2003-FY2008

(dollars in thousands)

	Total Program Level	MDUFMA User Fees	MDUFMA/ Total
FY2003 Actual	$217,285	$14,838	6.8%
FY2004 Actual	$179,245	$23,875	13.3%
FY2005 Actual	$244,282	$27,161	11.1%
FY2006 Actual	$255,041	$32,069	12.6%
FY2007 Pres. Budget	$271,571	$43,726	16.1%
FY2008 Pres. Budget	$285,376	$47,500	16.6%

Source: Food and Drug Administration tables for FY2005 - FY2008, "ALL PURPOSE TABLE - Total Program Level," at http://www.fda.gov/oc/oms/ofm/budget/documentation.htm.

Table 5. Full Time Employees (FTEs) in the Device Review Process, FY2003-FY2008

	Total Device Review FTEs	MDUFMA-Funded FTEs	MDUFMA-Funded / Total
FY2003 Actual	1,485	33	2.2%
FY2004 Actual	1,061	137	12.9%
FY2005 Actual	1,516	153	10.1%
FY2006 Actual	1,498	184	12.2%
FY2007 Pres. Budget	1,534	196	12.8%
FY2008 Pres. Budget	1,539	200	13.0%

Source: Food and Drug Administration tables for FY2005 - FY2008, "ALL PURPOSE TABLE - Total Program Level," at http://www.fda.gov/oc/oms/ofm/budget/documentation.htm.

MDUFA 2007 would increase the amount of fees and resulting FTEs each year until FY2012. Total fee revenues in FY2008 would increase by approximately 31% over estimated FY2007 fee revenues, and by 8.5% per year each subsequent year through FY2012, generating a total of $287 million over five years. (See **Table 6**.)

Table 6. Proposed MDUFA 2007 User Fee Revenue (S. 1082, H.R. 2900, and FDA Agreement) and Total Dollars Needed for the Device Review Process, FY2008-FY2012

	Total Device Review Program Requirement	MDUFMA User Fee Authorised Approps	MDUFMA/ Total
FY2008	$220,000	$ 48,431	22.0%
FY2009	$ 234,000	$ 52,547	22.5%
FY2010	$ 249,000	$ 57,014	22.9%
FY2011	$ 265,000	$ 61,860	23.3%
FY2012	$ 281,000	$ 67,118	23.9%

Source: FDA, "Medical Device User Fee and Modernization Act; Public Meeting," *Federal Register*, vol. 72, no. 74, p. 19528, (April 18, 2007) at http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=268837241492+0+0+0&WAISaction=retrieve.

Activities Requiring Fees, and Exceptions to the General Rule

MDUFMA gives FDA the authority to collect user fees from manufacturers seeking to market medical devices. All of the fees charged under MDUFMA are for types of applications required for FDA approval or clearance of a product. According to FDA, there were fluctuations in the number of applications submitted from year to year, and fee revenues repeatedly fell short of expectations.[11]

To remedy the situation, MDUFA 2007 would introduce three new types of fees, which would generate about 50% of the total fee revenue and that would be more stable than application fees. The new fees are an annual establishment registration fee (paid once each year by each manufacturer), an annual fee for filing periodic reports (applicable to Class III devices approved under PMAs, premarket reports, and PDP processes), and a fee for filing a 30-Day Notice. The FDA Agreement states that the implementation of these new fees would allow for significant reduction in MDUFA 2007 of existing application fees. (See **Table 7**.) Generally, fees would increase each year by 8.5%, which, according to FDA's recommendation, would ensure that fee revenues contribute their expected share to total program costs, and provide industry with stability and predictability in the fee revenues it would expect to pay. For the newly created establishment fee, the Secretary could increase the fee amount in FY2010 up to an additional 8.5% over the annual 8.5% increase if fewer than 12,250 establishments paid the fee in FY2009. This measure is designed to ensure that the fees collected from this source total 45% of total fee revenues.

Both MDUFMA and proposals for MDUFA 2007 set fees as a percentage of the full fee for a PMA, also called the *base fee*, which is generally the most involved type of application that a device manufacturer could make to FDA (FFDCA § 738(a)(2)(A)).[12] During the course of MDUFMA, the amount of the base fee (and thus the amounts of all of the other fees) rose each year, from $154,000 in FY2003 to $281,600 in FY2007 (FFDCA § 738(c)(1)). (See **Table 8**). The percentages of the base fee assigned to various types of submissions have changed slightly from MDUFMA to MDUFA 2007, but the concept is the same. The following is one example from MDUFA 2007: a 30-day notice fee is equal to 1.6% of the base fee.

MDUFA 2007 would strike a provision that enables the Secretary to adjust the premarket notification fee amount annually so that, in aggregate, these fees comprise a target amount. However, H.R. 2900 would maintain a reference to this deleted provision in the *Fee Amounts* section (21 U.S.C. 379j(a)(2)(A)).

Table 7. MDUFMA Fee Schedule, Current FY2007, Proposed FY2008-FY2012

Fees Structure	Current	Proposed MDUFA 2007				
	2007	2008	2009	2010	2011	2012
PMA/BLA	$281,600	$185,000	$200,725	$217,787	$236,298	$256,384
Sm. Bus.[a]	$107,008	$46,250	$50,181	$54,447	$59,075	$64,096

[11] FDA, "Medical Device User Fee and Modernization Act; Public Meeting," *Federal Register*, vol. 72, no. 74, p. 19528, (April 18, 2007) at http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=268837241492+0+0+0&WAISaction=retrieve.

[12] For more information, see the *PMA* subsection of the *Device Approval Process* portion of this report.

Fees Structure	Current	Proposed MDUFA 2007				
	2007	2008	2009	2010	2011	2012
Panel Track Supplements	$281,600	$138,750	$150,544	$163,340	$177,224	$192,288
Sm. Bus.[a]	$107,008	$34,688	$37,636	$40,835	$44,306	$48,072
180-Day Supplements	$60,544	$27,750	$30,109	$32,668	$35,445	$38,458
Sm. Bus.[a]	$23,007	$6,938	$7,527	$8,167	$8,861	$9,614
Real Time Supplements	$20,275	$12,950	$14,051	$15,245	$16,541	$17,947
Sm. Bus.[a]	$7,705	$3,237	$3,512	$3,810	$4,134	$4,485
510(k)	$4,158	$3,404	$3,693	$4,007	$4,348	$4,717
Sm. Bus.[a]	$3,326	$1,702	$1,847	$2,004	$2,174	$2,359
30-Day Notice		$ 2,960	$ 3,212	$ 3,485	$ 3,781	$ 4,102
Sm. Bus.[a]		$ 1,480	$ 1,606	$ 1,742	$ 1,890	$ 2,051
513(g)		$ 2,498	$ 2,710	$ 2,940	$ 3,190	$ 3,461
Sm. Bus.[a]		$ 1,249	$ 1,355	$ 1,470	$ 1,595	$ 1,731
Establishmt. Registration		$ 1,706	$ 1,851	$ 2,008	$ 2,179	$ 2,364
Annual Report Filing		$ 6,475	$ 7,025	$ 7,623	$ 8,270	$ 8,973
Sm. Bus.[a]		$ 1,619	$ 1,756	$ 1,906	$ 2,068	$ 2,243

Source: FDA, "Proposed Industry User Fee Schedule for MDUFA 2007," *Center for Devices and Radiological Health website*, (Updated April 16, 2007), at http://www.fda.gov/cdrh/mdufma/mdufmaii-comparison.html.

a. Sm. Bus. indicates the reduced small business fee associated with whatever item is listed above. (For more on the small business fee reduction, see the small business subsection below).

Table 8. MDUFMA Base Fee Rates, FY2003-FY2007

FY2003	FY2004	FY2005	FY2006	FY2007
$154,000	$206,811	$239,237	$259,600	$281,600

Source: "Fees" section, MDUFMA website of FDA's Center for Biologics Evaluation and Research (updated Aug. 2, 2006), at http://www.fda.gov/cber/mdufma/mdufma.htm.

Fee-Collection Offset

MDUFMA requires FDA to reduce fees in a subsequent year if collections in any year exceed the amount authorized, but does not have a parallel provision to increase fees in a subsequent year if collections fall short of amounts appropriated from fees. MDUFA 2007 would allow FDA to aggregate all fees collected from FY2008 through FY2011 and compare that amount to the aggregate amount authorized for the same period. A reduction would be made in fees in the final year only if the amount collected in the four-year period exceeded the amount authorized for the same period. According to the FDA Agreement, FDA believes this aggregation over four years will provide for greater financial stability for FDA than treating each year in isolation.

Fee Exceptions, Reductions, Refunds

Certain types of devices, sponsors and activities qualify for exceptions to certain fees, small businesses are charged a reduced rate.[13] These fee reductions, exemptions, and refunds are explained below. These are the same for MDUFMA and proposals for MDUFA 2007, except that the latter would qualify only federal or state Government Entities for an exemption from the new annual establishment registration fee, would expand and enhance the small business fee reduction, and would allow a partial refund for withdrawal of a particular kind of PMA, as explained below.

Humanitarian Use Devices (HUDs). HUD applications are exempt from MDUFMA fees. An HUD is a device that is intended to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States per year. A device manufacturer's research and development costs could exceed its market returns for diseases or conditions affecting small patient populations. FDA, therefore, developed and published this regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations. A qualifying manufacturer may submit a humanitarian device exemption (HDE) application, which is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA.

Devices Intended for Pediatric Use. In order to encourage the development of devices for use with children, any application for a device intended solely for pediatric use is exempt from any fee. If an applicant obtains an exemption under this provision, and later submits a supplement for adult use, that supplement is subject to the fee then in effect for an original PMA.

Applications from Federal or State Government Entities. Any application from a state or federal government entity is exempt from any fee, unless the device is to be distributed commercially. H.R. 2900 would include Indian tribes in the definition of government entities and thus exempt them from paying establishment fees; S. 1082 would not.

Further Manufacturing. In order to avoid the charging of multiple fees for single devices that have multiple manufactured components, any application for a product licenced for further manufacturing use only is exempt from any fee.

Premarket Notification by Third Parties. Under authority created by the Food and Drug Administration Modernization Act (P.L. 105-115), FDA has accredited third parties, authorizing them to conduct the primary review of 510(k)s for eligible devices. The purpose of the program is to improve the efficiency and timeliness of FDA's 510(k) process, the process by which most medical devices receive marketing clearance in the United States. No FDA fee is assessed for premarket notification (510(k)) submissions reviewed by accredited third parties, although the third parties may themselves charge a fee for their services.

Small Businesses. For FY2007 (MDUFMA, as modified by MDUFSA[14]), firms with annual gross sales or receipts of $30 million or less, including the gross sales and receipts of all affiliates, partners, and parent firms, qualify for a fee waiver for their first PMA. Firms with annual gross sales or receipts of $100 million or less, including the gross sales and receipts of all affiliates, partners, and parent firms, qualify for lower rates for all applications that are subject to a fee.[15]

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[13] Federal Food Drug and Cosmetic Act, sec. 738(a)(2)(B).

[14] MDUFSA increased the annual gross receipts or sales threshold below which businesses are eligible for reduced fees or a waiver of fees by the Secretary.

[15] Dan Schultz, "All-Hands Notice from Dan Schultz about MDUFA 2007," FDA website (April 16, 2007), at http://www.fda.gov/cdrh/mdufma/041607-letter.html.

The small business discounted fee schedule is important to the medical device industry; according to GAO, the vast majority of companies that paid MDUFMA fees in 2006 qualified as small businesses:

> Of the 697 companies that qualified as small businesses under the MDUFMA user fee program in fiscal year 2006, 656, or about 95%, had revenues at or below $30 million—the threshold for small business qualification originally set by MDUFMA in 2002. Of the 41 companies that had revenues above $30 million but at or below the current threshold of $100 million, 35 had revenues above $30 million but at or below $70 million. Of the 697 companies that qualified as small businesses in fiscal year 2006, two-thirds submitted at least one device application subject to user fees during that year. These companies were responsible for about 20% of the approximately 4,500 device applications subject to user fees that were submitted to FDA in fiscal year 2006.[16]

MDUFA 2007 would no longer consider the assets of partners and parent firms in the small business qualification calculation, and would further reduce the application fees paid by small business—the majority of device manufacturers.[17] For example, a small business would pay 50% of the standard fee when it submits a 510(k), compared with 80% at present, and 25% of the standard fee when it submits a PMA, compared with 38% at present. FDA would also continue to provide a fee waiver for the first PMA submitted by a qualified small business applicant. In addition, MDUFA 2007 would allow foreign businesses to qualify for small business fees and fee waivers.

Modular PMA Refunds. Manufacturers may choose to submit to FDA the large amount of information required in a PMA in sections, over time, in a *modular PMA*. In the event that a manufacturer chooses to withdraw a modular application before FDA takes its first action on the application or before all of the parts have been submitted, both bills provide that the Secretary may make a partial refund of the filing fee. S. 1082 specifies that the Secretary would have the sole authority to make refund decisions, and that such decisions would not be reviewable.

Use of Fees

According to the terms of MDUFMA, FDA may only use fees collected under MDUFMA for specified purposes (FFDCA § 737(5)). Most of these are related to decreasing the time required for FDA to determine whether a medical device should reach the marketplace. (See **Table 9**.) The payment of a MDUFMA premarket review fee is not linked in any way to FDA's final decision on whether a product should reach the market.[18]

[16] Government Accountability Office, "Food and Drug Administration: Revenue Information on Certain Companies Participating in the Medical Device User Fee Program," GAO-07-571R (March 30, 2007), at http://www.gao.gov/new.items/d07571r.pdf.

[17] FDA, "Medical Device User Fee and Modernization Act; Public Meeting," *Federal Register,* vol. 72, no. 74, p. 19528, (April 18, 2007) at http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=268837241492+0+0+0&WAISaction=retrieve.

[18] CDRH, "Summary of the Medical Device User Fee and Modernization Act of 2002 Including Changes Made by the Medical Devices Technical Corrections Act (April 1, 2004)," FDA website, (November 1, 2004), p. 2, at http://www.fda.gov/cdrh/mdufma/mdufmasummary.pdf. Visited January 22, 2007.

Table 9. Use of MDUFMA Fees

FDA may use MDUFMA fees for the following elements of the "process for the review of device applications"
• premarket reviews;
• premarket inspections;
• monitoring of research relating to premarket reviews;
• review of *investigational new drug applications* (INDs) and *investigational device exemptions* (IDEs);
• monitoring of research conducted to develop INDs or IDEs;
• development of guidance, policy documents, and regulations to improve the process for the review of device applications;
• development of test methods and standards applicable to premarket reviews;
• technical assistance to applicants;
• initial classification or reclassification of a device;
• actions required to call for PMAs for pre-Amendments Class III devices;
• evaluation of postmarket studies required as a condition of approval; and
• compiling, developing, and reviewing information concerning devices subject to premarket review to identify safety and effectiveness issues.

Source: 21 U.S.C. 379i(5); FFDCA §737(5).

MDUFA 2007 makes no change to MDUFMA's use of fees provision. The FDA Agreement had proposed that, as resources permit, FDA would apply user fee revenues to support reviewer training that is related to the process for the review of devices, including training to enhance scientific expertise. FDA would, in turn, provide summary information on the types of training provided to staff on an annual basis.

Performance Goals

In addition to enabling the collection of user fees, MDUFMA set performance goals for FDA. These goals were summarized in the FDA Commitment Letter, incorporated by reference in MDUFMA (§101(3)). (See **Table 10**.) The performance goals, but not the letter, are also included in the FFDCA (§738(g)(1)(A)-(D)). According to the FDA Agreement, FDA is on track to meet nearly all of the MDUFMA performance goals, which will sunset on October 1, 2007, along with FDA's MDUFMA user fee authority.

For purposes of MDUFA 2007, the FDA Agreement proposes to meet fewer and more rigorous goals that build on the progress made in MDUFMA. In making these proposals, FDA considered efficiencies gained and expected by means of additional scientific, regulatory, and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; expanded use of outside experts; and information technology improvements that allow FDA to better track and manage the device review process.

MDUFMA performance goals set general time tables for certain types of activities (such as PMA reviews), but allow for some flexibility that may be prudent, given different types of PMAs and other applications may vary in complexity. Therefore, performance goals generally state that, a certain percentage of the time FDA will complete a particular type of activity within a given time period (see **Table 10**).

Performance Goal-Setting Process

In FDA's development of its recommendations to the Congress for FDA performance goals and plans for meeting those goals, MDUFMA required FDA to consult with an array of governmental, professional, and consumer groups; publish its recommendations in the *Federal Register*; provide a public comment period; and hold a public meeting. MDUFA 2007 contains parallel provisions. In addition, the Senate version of the bill, S. 1082, specifies that the recommendations are to be revised upon consideration of public comments. Furthermore, S. 1082 would require transmittal of the recommendations to Congress and would write the relevant consultation requirements into the FFDCA.

Quarterly Performance Reports

The FDA Agreement specifies that FDA will report quarterly its progress toward meeting the quantitative goals described in this letter. In addition, for all submission types, FDA will track total time (time with FDA plus time with the company) from receipt or filing to final decision (approval, denial, substantial equivalence [SE], or nonsubstantial equivalence [NSE]). FDA will also provide, on an annual basis, de-identified review performance data for the branch (section of reviewers grouped by subject-matter) with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements.

Table 10. Comparison of Quantitative Decision Performance Goals in MDUFMA and MDUFA 2007

MDUFMA	MDUFA 2007
PMA and Panel Track Supplements	
50% of PMAs and panel track PMA supplements in 180 days	60% of PMAs and panel track PMA supplements in 180 days
90% of PMAs, panel track supplements, premarket reports in 320 days	90% of PMAs and panel track supplements in 295 days
N/A	50% of expedited PMAs and expedited panel track PMA supplements in 180 days
90% of expedited PMAs in 300 days	90% of expedited PMAs and expedited panel track PMA supplements in 280 days
Modular PMA	
N/A	75% of PMA modules in 90 days
N/A	90% of PMA modules in 120 days
510(k)s	
80% of 510(k)s in 90 days	90% of 510(k)s in 90 days
N/A	98% of 510(k)s in 150 days
180-Day PMA Supplements	
90% of 180-Day PMA supplements in 180 days	85% of 180-Day PMA supplements in 180 days 95% of 180-Day PMA supplements in 210 days
Real-Time PMA Supplements	
N/A	80% of Real-Time PMA Supplements in 60 days 90% of Real-Time PMA Supplements in 90 days

MDUFMA	MDUFA 2007
Biological License Applications	
90% of BLAs in 10 months 90% of BLA supplements in 10 months 90% of BLA resubmissions and BLA supplement resubmissions in 2 months	Same as MDUFMA

Source: FDA, "Comparison of Quantitative Decision Goals in MDUFMA and II," CDRH website,(Updated April 16, 2007) at http://www.fda.gov/cdrh/mdufma/mdufmaii-comparison.html.

Accredited Third-Party Inspections

Accredited third-party inspections were introduced in MDUFMA (as amended by MDTCA) with the goal of reducing the burden on FDA inspectors by enabling FDA-accredited persons (third parties) to conduct certain inspections on FDA's behalf. FDA is required, by statute, to inspect certain domestic establishments where medical devices are manufactured at least once every two years. According to the GAO, FDA has not been meeting this requirement.[19] Instead, five or six years sometimes pass between FDA inspections at any one establishment.

GAO reports that FDA accredited the first third party on March 11, 2004. As of October 31, 2006, of 23 organizations that had applied to conduct third-party inspections of establishments, 16 had received FDA accreditation, and seven had completed the necessary training and were cleared to conduct independent inspections. As of October 31, 2006, two accredited organizations had conducted independent inspections—one inspection of a domestic establishment and one inspection of a foreign establishment. During that same period, 36 inspections of domestic establishments and one inspection of a foreign establishment were conducted by accredited organizations jointly with FDA officials as part of training that FDA requires of accredited organizations. These 38 inspections represent just over 1% of the 3,470 inspections that FDA reported to GAO it conducted between March 11, 2004, and October 31, 2006.[20]

GAO reports that several factors may influence manufacturers' interest in voluntarily requesting an inspection by an accredited organization:

> According to FDA and representatives of affected entities, there are potential incentives and disincentives to requesting an inspection, as well as reasons for deferring participation in the program. Potential incentives include the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements and to control the scheduling of the inspection. Potential disincentives include bearing the cost for the inspection and uncertainty about the potential consequences of making a commitment to having an inspection to assess compliance with FDA requirements in the near future. Some manufacturers might be deferring participation. For example, manufacturers that already contract with a specific accredited organization to conduct inspections to meet the requirements of other countries might defer participation until FDA has cleared that organization to conduct independent inspections.[21]

[19] Government Accountability Office, "Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations," Report to Congress *GAO-07-157* (January 2007).

[20] This number includes both postmarket quality system inspections of domestic establishments where a Class II or III medical device was manufactured, and inspections of foreign medical device establishments.

[21] Government Accountability Office, "Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations," Report to Congress *GAO-07-157* (January 2007).

MDUFA 2007 would change the third-party accredited person inspection program in three major areas. According to the FDA Agreement, the proposals are intended to increase the quantity of useful information FDA has about the compliance status of medical devices marketed in the United States and to permit FDA to focus its inspectional resources on those firms and products posing the greatest risk to public health.

The first change would be to streamline the administrative burdens associated with qualifying for the program. For example, rather than having to petition FDA for clearance to use a third party, the proposal would require only that firms provide FDA with 30 days prior notice of their intent to use a third party listed on FDA's website.

The second change would be to expand participation in the program. For example, the current third-party program restricts qualified manufacturers of Class II and Class III medical devices to two consecutive third-party inspections, after which FDA must conduct the next inspection, unless the manufacturer petitions and receives a waiver. MDUFA 2007 would permit firms to use third parties for an unlimited number of consecutive inspections without seeking a waiver. However, FDA would continue to conduct "for cause" or follow-up inspections whenever it deemed such inspections appropriate.

The third change would be to permit device companies to voluntarily submit to FDA reports by third parties assessing conformance with an appropriate international quality systems standard, such as those set by the International Standards Organization. FDA would consider the information in these reports in setting its inspection priorities.

Reprocessed Single-Use Devices

Some reprocessed SUDs are relatively simple items for external use, such as inflatable sleeves to improve blood circulation, while others are complex and invasive, such as catheters that are inserted into the heart to monitor cardiac functioning. According to a GAO report issued in 2000 (prior to MDUFMA), some devices, both SUDs and those marketed as reusable, had been reprocessed in-house by hospitals and other treatment facilities, while others had been reprocessed by companies formed for that purpose.[22] At that time, the practice of SUD reprocessing raised public health concerns, primarily regarding the potential risks of infection and device malfunction, and led to complaints by the original device manufacturers that FDA had not maintained consistent regulatory standards for different types of medical device companies.

Before MDUFMA, the regulatory requirements for manufacturers of reprocessed single-use devices basically depended upon the class of the device. Manufacturers of reprocessed Class I and II single-use devices were required to have a 510(k), unless the device was exempt from 510(k). Reprocessors of Class III devices were required to obtain premarket approval. MDUFMA made reprocessors of some previously exempt devices no longer exempt from the 510(k) submission requirements. It required reprocessors to submit 510(k)s that include validation data. Validation data were also required for many reprocessors of single-use devices that were previously the subject of cleared 510(k)s. Finally, reprocessors of Class III devices needed to submit a premarket report (a new type of PMA) to FDA.

MDUSFA added the requirement that an SUD would be deemed as misbranded (and thus not legally marketable in the United States) unless it identified the manufacturer. MDUFSA allowed

[22] General Accounting Office, "Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted," GAO/HEHS-00-123 (June 2000), at http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.21&filename=he00123.pdf&directory=/diskb/wais/data/gao.

such information to be provided by a detachable label intended to be affixed to the medical record of a patient.

MDUFA 2007 does not focus on SUDs, but does contain a requirement that SUD reprocessors pay the proposed annual establishment fee.

Other MDUFA 2007 Provisions

In addition to the above provisions, as described below, MDUFA 2007 would require the production of several annual reports, and H.R. 2900 would authorize appropriations for postmarket surveillance and would require a study of nosocomial infections (those acquired in hospitals) related to medical devices.

Annual Reports

MDUFMA requires the Secretary to submit annual progress reports to relevant congressional committees regarding the progress of FDA in achieving fee-related performance goals specified in a letter from the Secretary, and regarding the implementation of the authority to collect such fees. H.R. 2900 would continue this requirement and specifies that the implementation report should include a description of the use of such fees for postmarket safety activities. S. 1082 would also continue the requirement, but instead of requiring that a description of postmarket safety activities be included in the implementation report, it would require the inclusion of information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications, supplements, and premarket notifications in the cohort. S. 1082 would also require that performance goal and implementation reports be made available to the public. In addition, unlike MDUFMA and H.R. 2900, S. 1082 would write the report requirements into the FFDCA.

Postmarket Safety Appropriations Authorization

MDUFMA contained two provisions related to postmarket reviews (§104). One, a provision that will cease to be effective on October 1, 2007, authorized additional appropriations for postmarket surveillance—$3 million for FY2003, $6 million for FY2004, and "such sums as may be necessary" in subsequent years. These sums were not appropriated. The second provision required the HHS Secretary to conduct a study of the postmarket review impact of the medical device user-fee program. MDUFMA also specified that user fees may fund the evaluation of postmarket studies if they are required as a condition of approval. (FFDCA §737(5)(J)).

According to FDA, MDUFMA focused on premarket review activities, largely limiting FDA's use of MDUFMA funds to this area, and focusing all performance goals on it as well. This emphasis on premarket activities raised some questions regarding whether this focus might have a negative impact on the postmarket and enforcement activities.

Measuring the impact of MDUFMA on enforcement activities is not a straightforward endeavor, and is beyond the scope of this report. For example, while one set of metrics (the number of CRDH warning letters issued each year since FY2000) shows that a decrease in the number of letters coincides with the start of MDUFMA, coincidence in time does not prove cause and effect. As is shown in **Table 11**, the recent decline in warning letters is due to a change in policy related to the Mammography Quality Standards Act (MQSA, P.L. 102-539).[23]

[23] For more information about CDRH enforcement statistics, see the CDRH Charts in FDA Office of Enforcement,

H.R. 2900 contains a different requirement relating to postmarket safety. It authorizes additional appropriations for FY2008-FY2012 of such sums as may be necessary for the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices. S. 1082 contains no parallel provision in the medical device user fee title.

Table 11. CDRH Warning Letters Issued in Total and Under the MQSA, FY2000-FY2007

	Non-MQSA	MQSA	Total
FY2000	191	337	528
FY2001	105	393	498
FY2002	75	206	285
FY2003	121	84	205
FY2004	193	5	198
FY2005	177	5	182
FY2006	149	5	154
FY2007[a]	47	5	52

Source: FDA Office of Legislation.

Note: According to FDA's Office of Legislation, the number of MQSA warning letters has significantly decreased because of a change in ORA and CDRH policy. Enforcement strategies for violations of the MQSA now focus on opportunities for correction and re-inspections (fees paid by facilities) prior to issuing warning letters. These measures have reduced the number of warning letters the program has had to issue.

a. Partial year, through February 1, 2007.

Nosocomial Infections

H.R. 2900 would define nosocomial infection as an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital. The bill would require the Comptroller General to conduct and deliver to Congress a study on the number of nosocomial infections attributable to new and reused medical devices and the causes of such infections. S. 1082 contains no parallel provisions.

Other MDUFMA Provisions

MDUFMA contained several provisions that have not been raised in MDUFA 2007 proposals:

- The review of combination products (products that combine elements of devices, drugs, or biologics) was to be coordinated by a new office in the Office of the Commissioner.
- Electronic labeling was authorized for prescription devices intended to be used in health care facilities.
- The sunset provision applicable to intended use based upon labeling (§513(i)(1)(E)) was revoked.
- MDUFMA explicitly provided for modular review of PMAs.

Office of Regulatory Affairs, "The Enforcement Story," (FY2006), at http://www.fda.gov/ora/about/enf_story/ch2/cdrh_charts.pdf.

- New provisions were added concerning devices intended for pediatric use.
- GAO and NIH were directed to prepare reports concerning breast implants.
- The manufacturer of a device was required to be identified on the device itself, with certain exceptions.

FDA Agreement Recommendations not in MDUFA 2007

While MDUFA 2007 generally followed the terms of the proposals made in the FDA Agreement, there were some topics covered in the Agreement that are not covered by MDUFA 2007. Their absence from the legislation does not preclude FDA from following the terms of the recommendations.

Interactive Review

The FDA Agreement proposes that FDA continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and sponsors to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and sponsors. Interactive review is intended to: (a) prevent unnecessary delays in the completion of the review; (b) avoid surprises to the sponsor at the end of the review process;(c) minimize the number of review cycles and the extent of review questions conveyed through formal requests for additional information; and (d) ensure timely responses from sponsors.

Guidance Document Development

The FDA Agreement proposes that FDA continue to develop guidance documents to the extent possible without adversely impacting the review timeliness for MDUFMA-related submissions. In addition, FDA would post a list of guidance documents it is considering for development and provide stakeholders an opportunity to provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

Diagnostic Imaging Products

Diagnostic imaging devices (e.g., CT scans) that are sometimes used concurrently with diagnostic drug and biological products (e.g., contrast agents and radiopharmaceuticals)—so-called "concomitant use products"—present important questions of efficient regulation and consultation between product Centers that are similar to those raised by combination products. In response to these concerns, the FDA Agreement proposes that FDA develop a guidance document to ensure timely and effective review of, and consistent, appropriate postmarket regulation and product labeling requirements for, diagnostic imaging devices used with approved imaging contrast agents and/or radiopharmaceuticals. FDA proposes to publish draft guidance by the end of FY2008 and allow for a 90-day public comment period. FDA proposes to issue a final guidance within one year of the close of the comment period.

In Vitro Diagnostics (IVDs)

To facilitate the development of IVD devices (lab tests), the FDA Agreement proposes that FDA continue to explore ways to clarify regulatory requirements and to reduce regulatory burden, as appropriate. FDA proposes to:

- Draft or revise guidance on the conduct of clinical trials involving deidentified leftover specimens, clinical trial design issues for molecular diagnostic tests, migration studies, herpes simplex virus, enterovirus, and influenza testing;
- Conduct a pilot program to evaluate integrating the 510(k) review and Clinical Laboratory Improvement Amendments (CLIA, (42 U.S.C. 263a) waiver review processes for possible increased efficiencies. This pilot would include only voluntary participants from industry, and the applications involved in the pilot would not be counted toward the MDUFA 2007 performance goals;
- Consider industry proposals on acceptable CLIA waiver study protocols, develop acceptable protocol designs, and make them available by adding appendices to the guidance or by posting redacted protocols on the Office of In Vitro Diagnostic Device (OIVD) website;
- Track and report FDA performance on CLIA waiver applications and share this information with industry annually and then evaluate, at the end of year two, whether user fees and performance goals for CLIA waivers should be considered for MDUFA 2007I;
- Review an industry-provided list of Class I and II low risk IVD devices to determine if any could be exempted from premarket notification and allow interested parties to petition for exemptions consistent with 510(m)(2) [provisions exempting certain devices from 510(k) premarket notification requirements]; and
- Conduct a review of the pre-IDE program to address issues raised by industry.

Meetings

The FDA Agreement proposes that FDA make every effort to schedule informal and formal meetings, both before and during the review process, in a timely way, and industry would make every effort to provide timely and relevant information to make the meetings as productive as possible.

Appendix. Acronyms Used in This Report

510(k)	Premarket Notification
513(g)	Request for Information About Device Classification
BLA	Biological License Application
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CLIA	Clinical Laboratory Improvement Amendments (42 U.S.C. 263a)
FDA	United States Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act (21 U.S.C., Chapter 9)
FTE	Full Time Equivalent Employee
GAO	Government Accountability Office (formerly General Accounting Office)
GMP	Good Manufacturing Practice
HHS	United States Department of Health and Human Services
HUD	Humanitarian Use Device
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IVD	In Vitro Diagnostic Device (Laboratory Diagnostic Test)
MDTCA	Medical Device Technical Corrections Act (P.L. 108-214)
MDUFMA	Medical Device User Fee and Modernization Act (P.L. 107-250)
MDUFA 2007	Medical Device User Fee and Modernization Act, 2007 Reauthorization
MQSA	Mammography Quality Standards Act (P.L. 102-539)
MUDFSA	Medical Device User Fee Stabilization Act of 2005 (P.L. 109-43)
NSE	Non-Substantial Equivalence
OIVD	Office of In Vitro Diagnostic Device
PDP	Product Development Protocol
PDUFA	Prescription Drug User Fee Act
PL	Public Law
PMA	Premarket Approval
SE	Substantial Equivalence
SUD	Single-Use Device
USC	United States Code

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